

CLAIMS

What is claimed is:

- 5 1. A composition comprising: extract of a plant *Prunella Linn* or *Rabdosia (Blume) Hasskarl* containing corosolic acid at a concentration of at least 0.01% by weight.
2. The composition of claim 1, wherein the concentration of corosolic
10 acid is at least 0.1% by weight.
3. The composition of claim 1, wherein the concentration of corosolic acid is at least 1% by weight.
- 15 4. The composition of claim 1, wherein the concentration of corosolic acid is at least 10% by weight.
5. The composition of claim 1, wherein the extract is an extract of the whole plant of *Prunella Linn* or *Rabdosia (Blume) Hasskarl*.
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6. The composition of claim 1, wherein the extract is an extract of the portion of the plant that grows above the ground.
7. The composition of claim 1, further comprising:
25 ursolic acid, 2 α , 19 α -dihydricursolic acid or daucosterol.
8. The composition of claim 1, wherein the corosolic acid is in a form of solid.
- 30 9. The composition of claim 1, wherein the extract is in a form of liquid.

10. A pharmaceutically acceptable composition, comprising:
a pharmaceutically acceptable excipient; and
extract of a plant *Prunella Linn* or *Rabdosis (Blume) Hasskarl*
5 containing corosolic acid at a concentration of at least 0.01% by weight.
11. The composition of claim 10, wherein the pharmaceutically acceptable composition is suitable for oral administration to a human.
- 10 12. The composition of claim 10, wherein the pharmaceutically acceptable composition is formulated with the excipient in a form selected from the group consisting of tablets, pills, dragees, capsules, emulsions, lipophilic and hydrophilic suspensions, liquids, gels, syrups, slurries, and suspensions.
- 15 13. The composition of claim 12, wherein the pharmaceutically acceptable composition is formulated in hard or soft-gel capsules.
14. The composition of claim 10, wherein the excipient is selected from
20 the group consisting of glycerol, sorbitol, lactose, magnesium stearate, maize starch, wheat starch, rice starch, potato starch, gelatin, gum tragacanth, methyl cellulose, hydroxypropylmethyl-cellulose, sodium carboxymethylcellulose, and polyvinylpyrrolidone.
- 25 15. The composition of claim 10, wherein the excipient is an pharmaceutically acceptable oil.
16. The composition of claim 15, wherein the pharmaceutically acceptable oil is selected from the group consisting of corn oil, wheat germ
30 oil, soy bean oil, rice bran oil, rapeseed oil, sesame oil, and fish oil.

17. The composition of claim 10, wherein the concentration of corosolic acid is at least 1% by weight.

5 18. The composition of claim 10, wherein the concentration of corosolic acid is at least 10% by weight.

19. The composition of claim 10, further comprising:
ursolic acid, 2α , 19α -dihydricursolic acid or daucosterol.

10 20. A method for lowering blood sugar levels of a mammal, comprising:
administering to the mammal a hypoglycemically effective amount of
an extract of a plant *Prunella Linn* or *Rabdosia (Blume) Hasskarl* containing
corosolic acid at a concentration of at least 0.01% by weight.

15 21. The method of claim 20, wherein the concentration of corosolic acid is
at least 1% by weight.

22. The method of claim 20, wherein the concentration of corosolic acid is
20 at least 10% by weight.

23. The method of claim 20, wherein the concentration of corosolic acid is
at least 50% by weight.

25 24. The method of claim 20, wherein the extract is orally administered to
the mammal.

25. The method of 20, wherein the extract administered to the mammal
via inhalation.

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26. The method of claim 20, wherein the mammal is a human.

27. The method of claim 26, wherein the human has a condition selected from the group consisting of hyperglycemia, hyperinsulinemia, dyslipidemia,
5 hypertension, hypercoagulation, obesity, type I and type II diabetic mellitus.

28. The method of claim 26, wherein the extract is administered to the human to deliver corosolid acid in an amount of 10-500 mg per day.

10 29. The method of claim 26, wherein the extract is administered to the human to deliver corosolid acid in an amount of 20-100 mg per day.

30. The method of claim 26, wherein the extract is administered to the human to deliver corosolid acid in an amount of 30-50 mg per day.

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31. The method of claim 20, further comprising:

administering to the mammal another hypoglycemic agent selected from the group consisting of insulin, metformin, buformin, sulfonylurea, acetohexamide, chlorpropamide, tolazamide, tolbutamide, glyburide,
20 glypizide, glyclazide, thiazolidinedione, troglitazone, acarbose, miglatol, CL-316 and CL-243.

32. The method of claim 20, wherein the extract is administered after being converted to pharmaceutically acceptable salts using a counter ion.

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33. The method of claim 32, wherein the counter ion is selected from the group consisting of sodium, potassium, lithium, calcium, magnesium, zinc and iron.

34. The method for manufacturing an extract of a plant *Prunella Linn* or *Rabdosia (Blume) Hasskarl* containing corosolic acid, comprising:

extracting a plant material from *Prunella Linn* or *Rabdosia (Blume) Hasskarl* in a first polar solvent such that the resulting extract contains
5 corosolic acid at a concentration of at least 0.01%.

35. The method of claim 34, wherein the concentration of corosolic acid is at least 1% by weight.

10 36. The method of claim 34, wherein the concentration of corosolic acid is at least 10% by weight.

37. The method of claim 34, wherein the concentration of corosolic acid is at least 50% by weight.

15 38. The method of claim 34, wherein the first solvent is an aqueous solution or organic solvent.

39. The method of claim 34, wherein the first polar solvent is selected
20 from the group consisting of methanol, ethanol, 2-methoxyethanol, 1-propanol, 2-propanol, iso-butanol, sec-butanol, tetrahydrofuran, and a mixture thereof.

40. The method of claim 34, wherein the first polar solvent is a mixture of
25 ethanol and water at a weight ratio of 3:1 to 10:1.

41. The method of claim 34, wherein the first polar solvent is ethanol with purity of at least 95%.

42. The method of claim 34, further comprising: grind the whole plant material or the portion grown above the ground.

43. The method of claim 34, wherein the ratio of the plant material and
5 the solvent is between 1:3 to 1:20 by weight.

44. The method of claim 34, wherein the ratio of the plant material and the solvent is between 1:5 to 1:10 by weight.

10 45. The method of claim 34, wherein the ratio of the plant material and the solvent is between 1:6 to 1:20 by weight.

46. The method of claim 34, wherein the plant material is extracted by heating for about 1- 24 hours at the reflux temperature of the first solvent.
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47. The method of claim 34, wherein the plant material is extracted by heating for about 3-8 hours at the reflux temperature of the first solvent.

48. The method of claim 34, further comprising: decolorizing the extract to
20 reduce the amount of chlorophyll in the extract.

49. The method of claim 48, wherein the extract is decolorized by using activated carbon.

25 50. The method of claim 34, further comprising:
partitioning the extract between the first solvent and an aliphatic solvent to reduce the amount of aliphatic molecules in the extract.

51. The method of claim 50, wherein the aliphatic solvent is petroleum
30 ether, solvent gasoline or a mixture thereof.

52. The method of claim 34, further comprising:
partitioning the extract in a biphasic mixture of a second polar and
second non-polar solvent to yield a crude extract of corosolic acid at
5 concentration of at least 0.1%.

53. The method of claim 52, wherein the second polar solvent is selected
from the group consisting of methanol, ethanol, acetone, 1-propanol, 2-
propanol, iso-butanol, sec-butanol, tetrahydrofuran, and a mixture thereof.
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54. The method of claim 52, wherein the second non-polar solvent is
selected from the group consisting of diethyl ether, ethyl acetate, isoamyl
acetate, benzene, toluene, xylene, 2-butanone, 4-methyl-2-pentanone,
chlorinated hydrocarbons such as dichloromethane, chloroform, carbon
15 tetrachloride, 1,2-dichloroethane, tetrachloroethylene, petroleum ether, and
a mixture thereof.

55. The method of claim 52, wherein the second polar solvent is ethanol
and the second non-polar solvent is chloroform, and the chloroform phase
20 containing the extracted corosolic acid is retained.

56. The method of claim 52, wherein the second polar solvent is acetone
and the second non-polar solvent is chloroform, and the acetone phase
containing the extracted corosolic acid is retained.
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57. The method of claim 34, further comprising:
purifying corosolic acid from the extract.

58. The method of claim 57, wherein corosolid acid is purified by
30 chromatography.

59. The method of claim 58, wherein the chromatography is selected from the group consisting of thin-layer chromatography, conventional silica gel chromatography, vacuum flash chromatography, high performance liquid
5 chromatography, and combinations thereof.

60. The method of claim 58, wherein the chromatography is silica gel chromatography and the eluent solvent for the chromatography is chloroform:acetone at a ratio of 60~90:40~10.
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61. The method of claim 34, further comprising:
crystallizing corosolic acid in the extract such that the purity of corosolic acid is at least 50%.

15 62. The method of claim 34, further comprising: crystallizing corosolic acid in the extract such that the purity of corosolic acid is at least 80%.

63. The method of claim 34, further comprising: crystallizing corosolic acid in the extract such that the purity of corosolic acid is at least 90%.
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64. The method of claim 34, further comprising: crystallizing corosolic acid in the extract such that the purity of corosolic acid is at least 98%.